REMARKS

Reconsideration and allowance of the above-identified application are respectfully requested. Claims 1-43 are pending, wherein claims 1, 2, 6, 15 and 23-27 have been amended, and new claims 28-43 have been added in order for Applicant to claim additional embodiments disclosed in the application.

I. INTRODUCTION

The present Application discloses and claims fiber-covered dental delivery instruments that solve a specific technical problem not previously understood or solved in the art. As set forth in the background of the Application:

> Another challenge within the art that relates to the delivery of dental compositions relates to the difficulty of accessing the sides of a dental surface, such as the interior surfaces of a cavity formed within the tooth of the patient. While it may be possible to deliver a dental composition to the top or bottom of a cavity or root canal from a delivery tip, it is often difficult to spread the composition on the interior walls of a cavity formed in the mouth without having to carefully manipulate the dispensing device.

Application, p. 4, lines 19-24. The present invention solves the foregoing technical problem as follows:

> It is yet another aspect of the invention, which may be employed with or without any other aspect of the invention, to provide a dental delivery instrument with which it is convenient to deliver a composition to the interior walls of [a] dental preparation, such as a formed cavity or root canal. This may be accomplished, at least in part, by the provision of a dental delivery instrument in the form of a delivery tip or applicator having a plurality of fibers on a distal rim thereof, and on the adjacent outer wall thereof.
>
> A portion of the fibers extend a length "L" distally beyond the rim of the hollow body and a portion of the fibers are coupled along the tubular wall a distance "D" proximally with respect to the rim. In the present invention, the distance "D" is at least about two and one-half times greater than the length "L" (*i.e.*, D = at least about 2.5L). Thus, the distance covered by fibers coupled to the tubular wall is significantly greater than the length extended past the rim of the delivery instrument. A variety of ratios are possible, such as wherein D = 2.5 L, 3 L, 4 L, 5 L, 6 L, 7 L, 8 L, 9 L, or 10 L or any fraction thereof or greater. One advantage is that these ratios apply for a variety of different dental delivery instruments, such as those discussed herein.

> Furthermore, by having fibers extending significantly along the length of the outer wall of the distal delivery end, it is possible to readily deliver and brush a dental composition both at the most remote point within a dental preparation and simultaneously along the interior wall surfaces of the preparation. The preparation may also be cleaned using the wall mounted fibers.
>
> On the other hand, other delivery designs that do not feature such wall-mounted fibers extending such a distance "D" along the outer wall must be awkwardly maneuvered in order the enable the fibers to adequately touch the interior walls in a manner so as to coat the walls with the dental composition.

Application, p. 9, lines 1-24 (emphasis added).

In drafting the current application, Applicant was aware of certain delivery devices of Centrix, Inc., which do not include wall mounted fibers that extend "such a distance 'D' along the outer wall". It was such delivery devices which Applicant found to be inadequate and that "must be awkwardly maneuvered in order to enable the fibers to adequately touch the interior walls in a manner so as to coat the walls with [a] dental composition". Such delivery devices of Centrix, Inc. are described in U.S. Patent No. 6,059,570 to Dragan et al. As such, including "wall-mounted fibers extending such a distance 'D' along the outer wall" (*i.e.*, a distance "D" of at least 2.5L, and in some cases a distance "D" of at least 3L, 4L or 5L or more depending on the delivery device and its intended use) is what provides fundamentally improved results over delivery devices such as those described in Dragan et al.

Accordingly, the present invention was specifically developed in an attempt to remedy and improve upon the problems inherent in the Dragan et al. delivery devices, namely, an insufficient distance "D" of wall-mounted fibers extending up the wall of such delivery devices. This problem inherent in the Dragan et al. delivery devices is neither understood nor addressed in Dragan et al. Each of the delivery devices disclosed in Dragan et al. includes an insufficient distance "D" of wall-mounted fibers. Dragan et al. nowhere teaches or suggests including a greater distance "D" of wall-mounted fibers for any reason whatsoever, let alone to provide improved delivery of dental composition onto the interior walls of a dental preparation. It therefore follows that Dragan et al. neither teaches nor suggests including wall mounted fibers having a distance "D" that is at least 2.5L (*i.e.*, the length "L" that the fibers extend distally beyond the rim of the hollow body of the delivery device). Dragan et al. is completely silent with respect to the problem of applying dental composition onto the interior walls of a dental

preparation and in providing a solution to this very important problem. The delivery devices disclosed and claimed in the present application solve this problem (*i.e.*, they eliminate or reduce the degree to which such devices must be "awkwardly maneuvered" in order to apply dental composition onto the interior walls of a dental preparation).

II. REJECTIONS UNDER 35 U.S.C. § 112, ¶ 2

The Office Action rejects claims 24-27 under 35 U.S.C. § 112, ¶ 2, for the reasons set forth in the Office Action at page 2. Accordingly, Applicant has amended these claims in order to address each of the concerns raised by the Examiner.

III. REJECTION UNDER 35 U.S.C. § 102(b)

The Office Action rejects claims 1, 2, 5, 8-10, 12-15, 20-23, and 25-27 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,829,976 to Green. Green discloses a tip 20 to which is attached "nonwoven tufted scrub material 18, comprised of materials such as nylon, polyurethane foam, or polyolefins". Col. 2, lines 55-58 (emphasis added). "The material is preferably a non-woven tufted material that completely surrounds the probe at 24. In contrast to brush bristles, several features of the scrub material 18 make it suitable for use in the invention". Col. 2, lines 61-64 (emphasis added). The "nonwoven tufted material" is shown in Figures 1 and 2 and roughly resembles a cotton swab. Green specifically distinguishes the "nonwoven tufted material" from "brush bristles", which comprise individual shafts of material attached at one end to an implement and which extend laterally away from the implement (*e.g.*, a brush). The "tufted material" can even be a polyurethane foam, which is completely non-fibrous. Col. 21, line 57. Green neither teaches nor suggests coupling a plurality of fibers to a hollow body in a manner so that the first ends of the fibers are "coupled to the hollow body and second ends extend[] laterally away from the hollow body". For this reason, claim 1 as presently amended is neither anticipated by nor obvious over Green. Support for the amendment to claim 1 is shown in the drawings (*e.g.*, Figures 1B, 2A, 2B, 1C, 2C, 2D, 3B, 34A, 34B, 34C and 35) and the written description accompanying such drawings.

Independent claims 15 and 23 were similarly amended and are neither anticipated by nor obvious over Green for the same reason. The dependent claims contain additional limitations that may serve to further distinguish over Green.

IV. REJECTION UNDER 35 U.S.C. §103(a)

The Office Action rejects claims 1-9 and 11-27 under 35 U.S.C. § 103(a) as being unpatentable under U.S. Patent No. 6,059,570 to Dragan et al. In making the rejection, the Office Action alleges that Dragan et al. "marginally show[s] the distance ['D'] is at least about two and one-half times greater than the length ['L']". Office Action, p. 4. Based on this characterization of Dragan et al., the Office Action then concludes that "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to have the distance of the fibers coupled along the wall at least about two and one-half times greater than the length of the fibers extending distally beyond the rim in order to enable the practitioner to spread or burnish the dental composition being dispensed by the tool onto the surface of the tooth in a continuous and expedient manner in view of Dragan et al." Office Action, p. 4. In response, Applicant will show that both the premise and conclusion do not follow from Dragan et al.

Figure 3, the only drawing relied upon in the Office Action, depicts a delivery device having fibers that extend 3 mm distally beyond the rim of the delivery device and 7 mm up the wall of the delivery device. 7 mm divided by 3 mm is yields a ratio of "D" to "L" of 2.3:1. The other figures in Dragan et al. depict delivery devices having smaller ratios of "D" to "L". For example, Figure 9 discloses a ratio of "D" to "L" that is significantly less than 2:1 (*i.e.*, "D" = 18 mm and "L" = 11 mm, which yields a ratio of 1.64). Figure 12 shows a fiber-covered delivery device that is angled into the page so as to artificially visually reduce the length "L" which, in turn, visually skews the actual relationship between "D" and "L". In any event, Dragan et al. does not disclose the actual relationship between "D" and "L" for any of the disclosed devices. Thus, whereas Dragan et al. discloses delivery devices in which the maximum ratio of "D" to "L" is arguably 2.3:1, Dragan cannot be interpreted as affirmatively teaching or suggesting delivery devices in which the minimum ratio of "D" to "L" is 2.5:1. Applicant notes that the term "about" has been removed from claims 1, 15 and 23, thus further distinguishing over Dragan et al.

As set forth in the present application, providing fibers that extend a length "L" beyond the rim of the delivery device and a distance "D" along the outer surface of the hollow body that is at least 2-1/2 times greater than "L" provides clear benefits and advantages over the delivery devices of Dragan et al., *i.e.*, the ability to more easily and less awkwardly apply dental materials within a dental preparation, particularly to both the bottom and interior walls of the dental

preparation. Dragan et al. completely fails to understand and address the problems associated with failing to provide a ratio of "D" to "L" that is at least 2.5:1. Instead, Dragan et al. teaches that the advantage of bonding fibers "adjacent the discharge opening" is so that "the user can exert pressure onto the surface of the tooth without causing the fibers to 'splay' or block the flow of dental material being expressed from the dental capsule or tip". Col. 2, lines 38-43 (emphasis added). "The arrangement is such that the fibers are bonded or adhered to the outer surface of the discharge nozzle so as to not obstruct the flow of material through the discharge nozzle as dental material is being expressed." Col. 2, lines 57-60; *see* col. 2, lines 60-67. Dragan et al. therefore provides fibers around the discharge opening to avoid obstructing the flow of dental material through the nozzle. Dragan et al. does not teach or suggest a solution to the problem of being able to apply a dental composition to both the bottom and interior walls of a dental preparation without having to awkwardly manipulate the delivery device.[1] In contrast, the delivery devices disclosed and claimed in the present application provide a technical solution to this problem. *See* Application, p. 4, lines 19-24; p. 9, lines 1-24.

For the reasons given above, Applicant submits that independent claims 1, 15 and 23 as amended are patentable and unobvious over Dragan et al. The dependent claims contain additional limitations that may further distinguish over Dragan et al. For example, dependent claims 12, 20 and 25 require that "distance 'D' is at least about three times greater than the length 'L'"; dependent claims 13, 21 and 26 require that "distance 'D' is at least about four times greater than the length 'L'"; and dependent claims 14, 22 and 27 require that "distance 'D' is at least about five times greater than the length 'L'". Including a distance "D" that is at least about 3, 4 or 5 times greater than the length "L" provides increasing benefits over Dragan et al. (*i.e.*, increased ability to apply dental composition onto interior walls of a dental preparation), thus further distinguishing over Dragan et al.

Notwithstanding the fact that Dragan et al. fails to address the problems associated with including too small of a ratio "D" to "L" of fibers along the outer wall of a delivery device (which problems are identified and remedied in the present application), the Office Action rejects claims 12-14, 20-22 and 25-27 by asserting, without citing to any teaching, suggestion, or

[1] Whether Dragan et al. can be argued to "inherently" provide tips that can simultaneously spread a dental composition onto the bottom and interior walls of a dental preparation is only relevant in the case of anticipation under 35 U.S.C. § 102. It is irrelevant in the case of obviousness under 35 U.S.C. § 103.

motivation in the art that "it would be an obvious matter of choice as to the specific ratio of the distance of the fibers coupled along the wall to the length of the fibers extending distally beyond the rim". Office Action, p. 4-5. In other words, the Office Action is in essence arguing that selecting the specific minimum ratios of "D" to "L" in dependent claims 12-14, 20-22 and 25-27 is merely the optimization of a result-effective variable through routine experimentation. See MPEP § 2144.05 (II. Optimization of Ranges).

The present application is clear that ensuring a minimum ratio of "D" to "L" of 2.5:1 significantly improves the ability to "readily deliver and brush a dental composition both at the most remote point within a dental preparation and simultaneously along the interior wall surfaces of the preparation". Application, p. 9, lines 18-19. Therefore, the ratios of "D" to "L" set forth in dependent claims 12-14, 20-22 and 25-27 (as well as in amended independent claims 1, 15 and 23) are indeed a type of result-effective variable that might arguably trigger a rejection under MPEP § 2144.05 (II. Optimization of Ranges). However, the MPEP is clear that only known or recognized result-effective variables can be optimized through routine experimentation; variables not previously not known to be result-effective are not optimizable through routine experimentation:

> A particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. *In re Antoine*, 559 F.2d 618, 195 USPQ 6 (CCPA 1977) (The claimed wastewater treatment device had a tank volume to contractor area of 0.12 gal./sq. ft. The prior art did not recognize that treatment capacity is a function of the tank volume to contractor ratio, and therefore the parameter optimized was not recognized in the art to be a result-effective variable.).

MPEP § 2144.05 (Subsection II.B.) (emphasis added).

The present case is remarkably similar to the facts of *In re Antoine* because the cited reference at issue (Dragan et al.) does not recognize that the relationship between distance "D" and length "L" is a result-effective variable (*i.e.*, Dragan et al. does not disclose or suggest any result-effective relationship between any particular ratio of "D" to "L" and the ability to deliver a dental composition within a dental preparation). Whereas Dragan et al. can be argued to inherently disclose a delivery device in which the fibers extend some length "L" beyond the rim

and some distance "D" up the outer surface of the wall, Dragan et al. is silent, and is therefore entirely unaware, that the relationship of "D" and "L" is a result-effective variable for any reason whatever, let alone to "readily deliver and brush a dental composition both at the most remote point within a dental preparation and simultaneously along the interior wall surfaces of the preparation". Application, p. 9, lines 18-19. Accordingly, both the MPEP § 2144.05 (Subsection II.B) and the CCPA in *In re Antoine* mandate a finding of nonobviousness when a claim recites a result-effective variable that is (i) not taught in the cited art and (ii) not recognized in the art as a result-effective variable. Such a case exists here where, as in *In re Antoine*, the cited art does not recognize the particular variable at issue (*i.e.*, the relationship between distance "D" and length "L") as being result-effective.

For this additional reason, Applicant submits that independent claims 1, 15 and 23, as well as dependent claims 12-14, 20-22 and 25-27 are patentable and nonobvious over Dragan et al., either alone or in combination with any art of record.

V. NEW CLAIMS 28-43

New claim 43 incorporates the limitations of claims 1, 4 and 10 into a single claim. Since dependent claim 4 was not rejected over Green et al. and dependent claim 10 was not rejected over Dragan et al., Applicant submits that new claim 43 is patentable over the art of record.

New dependent claims 28-42 claim additional embodiments disclosed at page 9, lines 12-13. These claims further distinguish over Dragan et al. because they claim a relationship of distance "D" to length "L" that is further removed from any relationship of "D" to "L" that can be reasonably argued to be disclosed in Dragan et al.

VI. CONCLUSIONS

In view of the foregoing, Applicant submits that the Application is presently in allowable form. In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, or that may be overcome by Examiner Amendment, the Examiner is requested to contact the undersigned attorney.

Dated this 13th day of January 2004.

Respectfully submitted,

JOHN M. GUYNN
Registration No. 36,153
Attorneys for Applicant
Customer No. 022913

JMG:mla

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